Remarks

Upon entry of the foregoing amendments, claims 1-12, 15-51, 54-59, 62-63, and 65-68 are pending in the application, with claims 1, 16, 49, 55, 56, and 63 being the independent claims. Claims 16, 49 and 50 are sought to be amended. New claims 66-68 are sought to be added. Claims 1-12, 15, 49-51, 54-59, 62, 63 and 65 are withdrawn from consideration. Claims 13-14, 52-53, 60-61, and 64 were cancelled by previous amendment without prejudice to or disclaimer of the subject matter therein.

Claims 16, 49 and 50 have been amended to more clearly define Applicants' invention by inserting the phrase "amphiphilic" immediately prior to "oligomer." Support for this amendment can be found in the specification, e.g., at page 16, paragraph [0062], and at page 26, paragraph [0098].

New claims 66-68 have been added. Support for these new claims can be found in the specification, e.g., at pages 100-105, and in claims 23 and 50 as originally filed. Excluding specifically described members of a Markush group does not violate the written description requirement. *See In re Johnson and Farnham*, 194 USPQ 187 (CCPA 1977).

These changes are believed to introduce no new matter and their entry is respectfully requested.

The Second Restriction and Election of Species Requirement

In reply to the second Restriction and Election of Species Requirement dated September 6, 2006, requesting an election of one invention to prosecute in the captioned patent application, Applicants hereby provide the following remarks.

In Applicants' Reply to the previous Restriction and Election of Species Requirement filed on June 12, 2006, Applicants provisionally elected to prosecute the invention of Group III, represented by claims 16-48, which are drawn to a method of treating a microbial infection in an animal by administering an effective amount of a pharmaceutical composition comprising an oligomer of Formula II. This election was made without prejudice to or disclaimer of the other claims or inventions disclosed. Applicants also provisionally elected the single oligomer of Formula II:

$$\mathbf{R^1\text{-}[\text{-}x\text{-}A_1\text{-}x\text{-}y\text{-}A_2\text{-}y\text{-}]_m\text{-}R^2} \qquad \textbf{(II)}$$

wherein: x is NR^8; R^8 is hydrogen; y is C=O; A_1 is *m*-phenylene substituted with one polar group and one non-polar group, wherein the polar group is $-(NR^{5'})_{q1PL}\text{-}U^{PL}\text{-}(CH_2)_{pPL}\text{-}(NR^{5'})_{q2PL}\text{-}V$ wherein U^{PL} is S, pPL is 2, q1PL and q2PL are 0, and V is amino, and the non-polar group is $-(NR^{3'})_{q1NPL}\text{-}U^{NPL}\text{-}(CH_2)_{pNPL}\text{-}(NR^{3''})_{q2NPL}\text{-}R^{4'}$ wherein U^{NPL} is absent, pNPL is 0, q1NPL and q2NPL are 0, and $R^{4'}$ is *t*-butyl; A_2 is unsubstituted pyrimidinylene; R^1 is the polar group $-(NR^{5'})_{q1PL}\text{-}U^{PL}\text{-}(CH_2)_{pPL}\text{-}(NR^{5'})_{q2PL}\text{-}V$ wherein U^{PL} is -C(=O)-, pPL is 4, q1PL and q2PL are 0, and V is guanidino; R^2 is $\text{-x-}A_1\text{-x-}R^1$ wherein x, A_1, and R^1 are as defined above; and m is 1. The oligomer elected by Applicants is disclosed in the captioned specification at page 100, as the third compound from the top of the page. Elected claims 16, 17, 22, 23, 24, 26, 27, 28, 31, 32, 35, 36, 37, 39, 41, 42, 43, 44, 46, and 47 read on this species. New claims 67 and 68 also read on this species.

On September 6, 2006, the U.S. Patent and Trademark Office (PTO) issued a second Restriction and Election of Species Requirement (PTO Paper No. 082906) in which the invention of previously-selected Group III (represented by claims 16-48) was

further restricted into 28 restriction groups based on the identity of the linkage between substituted oligomer backbone rings, the identity of the substituted rings (*i.e.*, aryl vs. heteroaryl), and the type of substitution present on each backbone ring (*i.e.*, whether each ring is substituted with polar vs. non-polar groups). Applicants were required to select one of these groups for prosecution, as well as an individual disclosed species (oligomer) representing the selected group.

In response to this second Restriction Requirement, Applicants wish to elect for further prosecution the group that encompasses the species oligomer of Formula II previously elected. However, Applicants cannot determine which group to elect because the previously-elected oligomer does not appear to fall within the scope of any of the twenty-eight restriction groups listed in the present Restriction Requirement. The A_1 arylene backbone ring in the previously-elected oligomer is substituted with both a polar group and a non-polar group, and the A_2 ring is unsubstituted. None of the 28 restriction groups described in the Restriction Requirement permit the A_1 and A_2 backbone rings to be substituted with of a combination of polar and non-polar groups, or permit a combination of arylene and heteroarylene backbone rings. Neither do the 28 restriction groups appear to permit the presence of backbone rings that are unsubstituted, because none of the 28 groups indicate that the rings are *optionally* substituted.

As an alternative, Applicants would elect one of the oligomers of Formula II listed on pages 100-105 of the specification, but, again, none of these oligomers appear to fall within the scope of any of the twenty-eight restriction groups listed in the present Restriction Requirement, for the same reasons. Nor, for that matter, do any of the individual oligomers of Formula II disclosed throughout the entire specification appear

to fall within the scope of any of the twenty-eight restriction groups, again for the same reasons. Virtually all of the individual oligomers of Formula II - and of Formulae I and IV - disclosed in the specification contain backbone rings that are substituted with a combination of one or more polar group(s) and one or more non-polar group(s), contain an unsubstituted backbone ring, and/or contain a combination of arylene and heteroarylene backbone rings.

Applicants also note that, contrary to the Restriction Requirement, dependent claims 22, 23, 24, 25 and 48 recite oligomers of Formula II that do not appear to fall within the scope of any of the 28 restriction groups, again, for the same reasons. For example, claims 22 and 23 recite oligomers that contain a combination of arylene and heteroarylene backbone rings. Claims 24, 25, and 48 recite oligomers that contain a backbone ring substituted with both a polar group and a non-polar group.

The individual oligomers of Formula II disclosed in the specification represent embodiments of Applicants' invention. If the PTO alleges that Applicants' claims 16-48 represent multiple independent or distinct inventions and requires Applicants to select one invention for prosecution, then the PTO ought to present Applicants with one or more restriction groups that actually encompass disclosed embodiments of those inventions presented in Applicants' specification and claims.

Claims 16-48 are directed to the use of the claimed amphiphilic oligomers in a method of treating a microbial infection in an animal. The oligomers recited in the claims are amphiphilic. The term "amphiphilic" is defined in the specification, at page 26, paragraph [0098], as describing a three-dimensional structure (e.g., an oligomer) having discrete hydrophobic and hydrophilic regions, including, e.g., amphiphilic

oligomers having polar (hydrophilic) and non-polar (hydrophobic) side chains that adopt conformations leading to the segregation of the polar and non-polar side chains to separate regions of the oligomer. See pages 26-27, paragraph [0100], of Applicants' specification. Thus, the oligomers must have polar and non-polar regions, either inherently or in the form of polar and non-polar groups substituted on the aryl and heteroaryl rings of the backbone. The amphiphilicity of the oligomers is central to their anti-microbial activity. See Applicants' specification, e.g., at page 16, paragraph [0062].

None of the 28 restriction groups from which Applicants have been allowed to choose allow for amphiphilicity. As discussed above, the 28 groups require both of the backbone rings A_1 and A_2 of the oligomers to be substituted with either all polar groups or all non-polar groups, but not a combination of polar and non-polar groups which would provide amphiphilicity. Similarly, several of the oligomers disclosed in the specification possess a combination of aryl and heteroaryl backbone rings, yet none the 28 restriction groups allow for oligomers having a combination of aryl and heteroaryl backbone rings. Restriction of Applicants' invention into the 28 different groups listed in the current Restriction Requirement is therefore meaningless because the groups do not permit the property of amphiphilicity, which is a central feature of Applicants' invention.

Because the 28 restriction groups presented in the Restriction Requirement are not meaningful in light of Applicants' invention, and because Applicants are required to select a restriction group for further prosecution, Applicants request the Examiner to indicate a group that reads upon the oligomer of Formula II listed above that Applicants previously selected in the first Restriction and Election of Species Requirement. As noted above, this oligomer is disclosed in the captioned specification at page 100, as the

third compound from the top of the page. Elected claims 16, 17, 22, 23, 24, 26, 27, 28, 31, 32, 35, 36, 37, 39, 41, 42, 43, 44, 46, and 47 read on this species. New claims 67 and 68 also read on this species. If the Examiner chooses to select one of the 28 groups, then Applicants respectfully request that the Examiner point out with particularity exactly how the selected species oligomer falls within the scope of the selected restriction group.

This election is made **with** traverse. Applicants request that the Examiner withdraw the present Restriction Requirement.

First, as discussed above, the 28 restriction groups presented in the Restriction Requirement are not only burdensome to Applicants but also ignore a central feature of Applicants' invention, amphiphilicity, and do not allow for a meaningful restriction of any of Applicants' inventions.

Second, the Examiner has restricted within each of claims 16-48, *i.e.*, has attempted to separate the oligomers of a single claim into individual restriction groups. Restriction practice is not applicable to a single claim (See *In re Weber*, 198 U.S.P.Q. 332 (C.C.P.A. 1978) and its companion case, *In re Haas*, 198 U.S.P.Q. 334 (C.C.P.A. 1978)). These cases make it clear that 35 U.S.C. § 121 does not grant to the PTO the authority to refuse to examine a single claimed invention. Section 121 only applies to *plural* claimed inventions in *different* claims, wherein the different claims vary not just in scope, but in the invention to which each is directed.

The Manual of Patent Examining Procedure (MPEP), 8th Ed. (August 2006), at § 803.02, page 800-5, left-hand column, second paragraph, states that "it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention" and that unity of invention exists

where the compounds of the claim "(1) share a common utility, and (2) share a substantial structural feature essential to that utility." Claims 16-48, as currently presented, recite amphiphilic oligomers which all share the common structural feature of amphiphilicity and the common utility of effectiveness in the claimed method. The amphiphilic oligomers recited in claims 16-48 share unity of invention. Thus, restriction should not be required within each claim.

Third, even if Applicants' claims encompass multiple independent and distinct inventions, the Examiner must examine all the claims if the search and examination of the claims can be made without serious burden. Manual of Patent Examining Procedure, 8th Ed. (August 2006), § 803, at page 800-4, left-hand column, lines 1-16.

The 28 groups in the current Restriction Requirement fall into only 7 separate classifications based on the identity of the ring linkage, *i.e.*, there are 7 sets of 4 restriction groups, the four groups within each set having the same classification. Applicants submit that, by the Examiner's own admission, it would not be a burden on the Examiner to search the four groups in each set together.

For example, groups I, VIII, XV, and XXII should be examined together because they share the same classification (514/675) and encompass oligomers in which the backbone rings are connected by an amide linkage. It would not be a burden on the Examiner to search these four groups together because a search concerning the patentability of the invention of one group is likely to uncover art of interest to the other group. Similarly, groups II, IX, XVI, and XXIII (encompassing oligomers having an ester linkage, all classified in 514/506) should be examined together; groups III, X, XVII, and XXIV (encompassing oligomers having a thiol linkage, all classified in

514/706) should be examined together; groups IV, XI, XVIII, and XXV (oligomers having a sulfonamide linkage, all classified in 514/600) should be examined together; groups V, XII, XIX, and XXVI (oligomers having a sulfonate linkage, all classified in 514/709) should be examined together; groups VI, XIII, XX, and XXVII (oligomers having a thiocarboxamide linkage, all classified in 514/599) should be examined together; and groups VII, XIV, XXI, and XXVIII (oligomers having a pyromellitic diimide linkage, all classified in 514/241) should be examined together.

Thus, a search of any of these groups together would not impose any burden upon the Examiner.

Applicants suggest that a search and examination of the elected species can be made in a straight-forward manner by expanding the search based upon the identity of the linkage between the rings in the oligomer backbone (e.g., x and y together form an amide), rather than the identity of the substitution groups on the backbone rings (polar vs. non-polar) or by the identity of the backbone rings (aryl vs. heteroaryl). The Examiner has already placed those restriction groups requiring that x and y together form the same linkage in the same classification. For example, as described above, groups I, VIII, XV, and XXII, each of which require that x and y form an amide linkage between the A_1 and A_2 backbone rings, are listed as being within the same classification, 514/675.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested.

Conclusion

Applicants believe that a full and complete reply has been made to the Restriction and Election of Species Requirement, and prompt and favorable consideration of this Amendment and Reply is respectfully requested. It is respectfully believed that this application is now in condition for examination. Early notice to this effect is respectfully requested.

Respectfully submitted,

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